UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,732	09/29/2006	Eita Ichige	04853.0139	9494

22852 7590 05/14/2008

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
05/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,732	ICHIGE ET AL.	
	Examiner	Art Unit	
	IQBAL H. CHOWDHURY	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-12 are pending in this application.

This application is a 371 of PCT/JP05/06730.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group, I claim(s) 1-7 (in part), drawn to a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix A region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, II claim(s) 1-7 (in part), drawn to a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the beta- sheet 2 region of amino acid between 32 and 36 of SEQ ID NO: 2.

Group, III claim(s) 1-7 (in part), drawn to a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 163 of SEQ ID NO: 2.

Group, IV claim(s) 1-7 (in part), drawn to a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 165 of SEQ ID NO: 2.

Group, V claim(s) 1-7 (in part), drawn to a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 169 of SEQ ID NO: 2.

Group, VI claim(s) 1-7 (in part), drawn to a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 172 of SEQ ID NO: 2.

Group, VII claim(s) 1-7 (in part), drawn to a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 173 of SEQ ID NO: 2.

Group, VIII claim(s) 1-7 (in part), drawn to a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 174 of SEQ ID NO: 2.

Group, IX claim(s) 1-3 and 7 (in part), drawn to a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix A region of amino acid between 15 and 28 of SEQ ID NO: 4.

Group, X claim(s) 1-3 and 7 (in part), drawn to a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the beta- sheet 2 region of amino acid between 32 and 36 of SEQ ID NO: 4.

Group, XI claim(s) 1-3 and 7 (in part), drawn to a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 4.

Group, XII claim(s) 8 and 9-10 (in part), drawn to a DNA molecule encoding a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix A region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, XIII claim(s) 8 and 9-10 (in part), drawn to a DNA molecule encoding a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the beta sheet 2 region of amino acid between 32 and 36 of SEQ ID NO: 2.

Group, XIV claim(s) 8 and 9-10 (in part), drawn to a DNA molecule encoding a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 163 of SEQ ID NO: 2.

Group, XV claim(s) 8 and 9-10 (in part), drawn to a DNA molecule encoding a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 165 of SEQ ID NO: 2.

Group, XVI claim(s) 8 and 9-10 (in part), drawn to a DNA molecule encoding a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix A region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 169 of SEQ ID NO: 2.

Group, XVII claim(s) 8 and 9-10 (in part), drawn to a DNA molecule encoding a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 172 of SEQ ID NO: 2.

Group, XVIII claim(s) 8 and 9-10 (in part), drawn to a DNA molecule encoding a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 173 of SEQ ID NO: 2.

Group, XIX claim(s) 8 and 9-10 (in part), drawn to a DNA molecule encoding a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 1621 and 173 of SEQ ID NO: 2 or at position 174 of SEQ ID NO: 2.

Group, XX claim(s) 8 and 9-10 (in part), drawn to a DNA molecule encoding a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix A region of amino acid between 15 and 28 of SEQ ID NO: 4.

Group, XXI claim(s) 8 and 9-10 (in part), drawn to a DNA molecule encoding a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the beta-sheet 2 region of amino acid between 32 and 36 of SEQ ID NO: 4.

Group, XXII claim(s) 8 and 9-10 (in part), drawn to a DNA molecule encoding a modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix A region of amino acid between 162 and 173 of SEQ ID NO: 4.

Group, XXIII claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix A region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, XXIV claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the beta-sheet 2 region of amino acid between 32 and 36 of SEQ ID NO: 2.

Group, XXV claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 163 of SEQ ID NO: 2.

Group, XVI claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 165 of SEQ ID NO: 2.

Group, XXVII claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 169 of SEQ ID NO: 2.

Group, XXVIII claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 172 of SEQ ID NO: 2.

Group, XXIX claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at

least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 173 of SEQ ID NO: 2.

Group, XXX claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 162 and 173 of SEQ ID NO: 2 or at position 174 of SEQ ID NO: 2.

Group, XXXI claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, XXXII claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, XXXIII claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, XXXIV claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, XXXV claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, XXXVI claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, XXXVII claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, XXXVIII claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, XXXIX claim(s) 11 (in part), drawn to a method for producing optically active cyanohydrin by using the modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region of amino acid between 15 and 28 of SEQ ID NO: 2 or at position 21 of SEQ ID NO: 2.

Group, XXXX claim(s) 12 (in part), drawn to a method for improving stability of modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix A region.

Group, XXXXI claim(s) 12 (in part), drawn to a method for improving stability of modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the beta-sheet 2 region.

Group, XXXXII claim(s) 12 (in part), drawn to a method for improving stability of modified S-hydroxynitrile lyase, which is obtained by modifying at least one amino acid in the helix D3 region.

For each inventions I-XXXXII above, restriction to one of the following is also required under 35 U.S.C. 121 and 372. Therefore, election is required of one of inventions I-XXXXII **and** one of inventions (A) – (L).

(A). protein of SEQ ID NO: 6 or a nucleic acid encoding SEQ ID NO: 6.

(B). protein of SEQ ID NO: 8 or a nucleic acid encoding SEQ ID NO: 8.

(C). protein of SEQ ID NO: 16 or a nucleic acid encoding SEQ ID NO: 16.

(D). protein of SEQ ID NO: 20 or a nucleic acid encoding SEQ ID NO: 20.

(E). protein of SEQ ID NO: 22 or a nucleic acid encoding SEQ ID NO: 22.

(F). protein of SEQ ID NO: 26 or a nucleic acid encoding SEQ ID NO: 24.

(G). protein of SEQ ID NO: 28 or a nucleic acid encoding SEQ ID NO: 28.

(H). protein of SEQ ID NO: 32 or a nucleic acid encoding SEQ ID NO: 32.

(I). protein of SEQ ID NO: 36 or a nucleic acid encoding SEQ ID NO: 36.

(J). protein of SEQ ID NO: 40 or a nucleic acid encoding SEQ ID NO: 40.

(K). protein of SEQ ID NO: 42 or a nucleic acid encoding SEQ ID NO: 42.

(L). protein of SEQ ID NO: 44 or a nucleic acid encoding SEQ ID NO: 44.

2. The inventions listed as Groups I-XXXXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The polynucleotide encoding modified polypeptide hydroxy nitrile lyase (HNL) of Groups XII-XXII, and modified polypeptide hydroxy nitrile lyase (HNL) of Groups I-XI, are each unrelated and chemically distinct entities. The only shared technical feature of these groups is that they all relate to wild type polynucleotide encoding a polypeptide hydroxy nitrile lyase or wild type polypeptide hydroxy nitrile lyase either from Manihot esculenta (SEQ ID NO: 2) or Hevea brasiliensis (SEQ ID NO: 4), (although claim 1 does not require any specific HNL). However, this shared technical feature is not a "special technical feature" as defined by PCT Rule 13.2 as it does not define a contribution over the art. The polypeptide of SEQ ID NO: 2 or 4 having HNL activity and corresponding nucleic acid sequence encoding them are known in the art, i.e. 100% identical (UniProt Accession No. P52705 for SEQ ID NO: 2, created 10/01/1996 and WO 97/03204-A2 (see IDS) for SEQ ID NO: 4, publication 01/30/1997; see sequence alignment). Thus, a modified HNL based on SEQ ID NO: 2 or 4 does not make contribution over the prior art.

3. The methods of Groups XXIII-XXXXII do not share any "special technical feature" with Groups XII-XXII as the polynucleotides of Groups XII-XXII are neither made nor used by the method of Groups XXIII-XXXXII.

4. The methods of Groups XXIII-XXXXII do not have unity of invention with each other as each methods comprises unrelated steps, and use different products, and produce different effects.

5. The proteins of Group (A)-(L) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different proteins of Group (A)-(L), which are polypeptides having HNL activity, do not have special technical feature among each other because they all represent structurally different polypeptides and polynucleotide encoding them. As mentioned above, the polypeptides of SEQ ID NO: 2 and 4 having HNL activity are known in the art and do not make contribution over the prior art. Therefore, they (all the inventions) lack special technical feature.

37 CFR 1.475 does not provide for multiple products and/or methods within a single application. Therefore, inventions of Group I - XXXXII lack unity of invention.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either

instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal H. Chowdhury, Ph.D., Patent Examiner
Art Unit 1652 (Recombinant enzymes)
Rm. REM 2B69, Mail Box- 2C70
US Patent and Trademark Office
Ph. 571-272-8137, Fax. 571-273-8137

/Iqbal H. Chowdhury/
Patent Examiner, Art Unit 1652